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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,194	07/11/2003	Eva M. Sevick-Muraca	017575.0700	4277

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BAKER BOTTS L.L.P.  
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DALLAS, TX 75201-2980

EXAMINER
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WINAKUR, ERIC FRANK

ART UNIT	PAPER NUMBER
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3768

NOTIFICATION DATE	DELIVERY MODE
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09/03/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ptomail1@bakerbotts.com  
glenda.orrantia@bakerbotts.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/618,194	<b>Applicant(s)</b> SEVICK-MURACA ET AL.	
	<b>Examiner</b> Eric F. Winakur	<b>Art Unit</b> 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/16/09</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 15 - 23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification provides details of imaging fluorescence from lymph nodes. However, there is no disclosure of quantitative analysis of data, nor is there disclosure of establishing values corresponding to a level of fluorescence at different positions, where the level varies with a composition of the sentinel lymph node. As such, the specification does not enable one to make or use the claimed invention.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 5, 8, 10, 13, 14, and 15 - 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With regard to claims 5, 10, and 15, it is unclear how one can modulate an intensity to obtain light of a particular wavelength range, as the claim appears to set forth, since varying intensity is not generally associated with shifting a wavelength. With regard to claim 8, the group

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recited in the claim does not appear to set forth a further limitation, since all fluorescent contrast agents will necessarily be either a non-specific or a specific fluorescent contrast agent. With regard to claim 13, it is unclear what how the limitation of the claim further limits the structure of claim 7, as it does not appear that the particular lymph node being detected requires adaptation of any of the claimed elements. With regard to claim 14, the phrase "the imaging device" lacks antecedent basis.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1 - 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayashi in view of Chance. Hayashi teaches a sentinel lymph node detection method and system that includes providing a subject with a contrast agent (indocyanine green), applying stimulating light, imaging the resulting fluorescence (Figures 2 and 5 and the descriptions thereof in columns 8, 10, 11). The detecting includes filtering the stimulation light before detecting the fluorescence wavelengths. However, Hayashi does not particularly teach the use of time-varying excitation light. Chance teaches an alternate optical measurement arrangement that includes modulating input light for imaging. Further, Chance teaches the technique is suitable for use in fluorescent contrast imaging (column 11, lines 8 - 17). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Hayashi to include

modulating the excitation light, as taught by Chance, since Chance teaches that this is suitable for use in fluorescent contrast imaging.

7. Claims 7 - 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayashi in view of Chance and Gratton. Hayashi teaches a sentinel lymph node detection method and system that includes providing a subject with a contrast agent (indocyanine green), applying stimulating light, imaging the resulting fluorescence (Figures 2 and 5 and the descriptions thereof in columns 8, 10, 11). The detecting includes filtering the stimulation light before detecting the fluorescence wavelengths. However, Hayashi does not particularly teach the use of time-varying excitation light. Chance teaches an alternate optical measurement arrangement that includes modulating input light for imaging. Further, Chance teaches the technique is suitable for use in fluorescent contrast imaging (column 11, lines 8 - 17). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Hayashi to include modulating the excitation light, as taught by Chance, since Chance teaches that this is suitable for use in fluorescent contrast imaging. However, Hayashi and Chance does not particularly discuss including an image intensifier in their arrangement. Gratton teaches including an image intensifier prior to a CCD detector in a modulated optical signal imaging arrangement (Figure 1, element 16; column 8, lines 9 - 26; column 8, line 65 - column 9, line 11). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the combination of Hayashi and Chance to include an image intensifier, as taught by Gratton, since this allow improved detection of optical signals.

***Response to Arguments***

8. Applicant's arguments, see Remarks, filed 8/4/08, with respect to the rejection(s) of claim(s) 1 - 14 under 35 USC 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the art as applied above.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric F. Winakur whose telephone number is 571/272-4736. The examiner can normally be reached on M-Th, 7:30-5; alternate Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571/272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/  
Primary Examiner, Art Unit 3768